

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

THE MUSCOGEE (CREEK) NATION)	Case No. 1:18-op-45459
)	
PLAINTIFF,)	JUDGE DAN AARON POLSTER
v.)	
)	ANSWER AND AFFIRMATIVE
)	DEFENSES
PURDUE PHARMA L.P.; et al.,)	(MDL Case No. 17-md-2804)
)	
DEFENDANTS.)	Trial by Jury Demanded

**DEFENDANT M&D STAR DRUG, INC.'S ANSWER AND AFFIRMATIVE DEFENSES
TO PLAINTIFF'S FIRST AMENDED COMPLAINT**

COMES NOW Defendant M&D Star Drug, Inc., and hereby submits this Answer and Affirmative Defenses to the First Amended Complaint filed by Plaintiff The Muscogee (Creek) Nation (Doc. #731).

Unless expressly stated otherwise, M&D Star Drug denies each and every allegation contained in the First Amended Complaint, including any averments contained in the preamble, unnumbered and numbered paragraphs, titles, headings, subheadings, table of contents, footnotes, exhibits, characterization of documents, and stricken paragraphs, and specifically denies any liability to Plaintiff. To the extent not expressly denied, all averments for which M&D Star Drug denies possessing knowledge or information sufficient to form a belief are denied. M&D Star Drug reserves the right to seek to amend and supplement its Answer as may be appropriate or necessary.

RESPONSES TO PLAINTIFF'S AVERMENTS

1. In response to paragraph numbered 1, M&D Star Drug admits that prescription opioids can reduce pain, help certain patients manage their pain, and pose certain risks.

2. In response to paragraph numbered 2, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them.

3. To the extent the averments in paragraph numbered 3 are directed to Defendants other than M&D Star Drug, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

4. The averments in paragraph numbered 4 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

5. The averments in paragraph numbered 5 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

6. In response to paragraph numbered 6, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments therein and therefore denies them. To the extent the averments contained therein can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

7. In response to paragraph numbered 7, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent the averments contained therein can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

8. In response to paragraph numbered 8, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. To the extent the averments contained therein can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

9. M&D Star Drug admits that certain companies manufacture opioid medications, then transfer those medications to other companies that act as distributors, which then transfer the opioid medications to pharmacies and other entities, which then dispense such medications to patients.

10. The averments in paragraph numbered 10 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

11. The averments in paragraph numbered 11 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To

the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

12. To the extent the averments in paragraph numbered 12 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent that the averments in paragraph numbered 12 can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

13. In response to paragraph numbered 13, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

14. In response to paragraph numbered 14, admits that prescription opioid medications are regulated by Federal and State governmental authorities. To the extent the averments in paragraph numbered 14 are directed to Defendants other than M&D Star Drug, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

15. To the extent the averments in paragraph numbered 15 are directed to Defendants other than M&D Star Drug, M&D Star Drug lacks knowledge sufficient to form a belief as to the

truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

16. In response to paragraphs numbered 16 through 19, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

17. To the extent the averments in paragraph numbered 20 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

18. In response to paragraph numbered 21, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

19. In response to paragraph numbered 22, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, illicit opioids such as heroin, and other drugs, represent a public health crisis. M&D Star Drug lacks knowledge

sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

20. In response to paragraph numbered 23, M&D Star Drug states that the averments and causes of action set forth in Plaintiff's First Amended Complaint speak for themselves. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

21. In response to paragraph numbered 24, M&D Star Drug states that the prayer for recovery set forth in Plaintiff's First Amended Complaint speaks for itself. To the extent paragraph numbered 24 can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

22. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 25 and therefore denies them.

23. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments contained in paragraph 26 and therefore denies them.

24. To the extent the averments in paragraph numbered 27 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent that the averments in paragraph numbered 27 can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

25. The averments contained in paragraphs numbered 28 through 86 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required.

26. With respect to the averments contained in paragraph numbered 87, M&D Star Drug admits it is an Oklahoma business entity with its principal place of business in Oklahoma, is authorized to do business in Oklahoma, and has dispensed prescription opioids in Oklahoma. M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the remaining averments and therefore denies them.

27. The averments contained in paragraphs numbered 88 through 91 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required.

28. M&D Star Drug denies the averments contained in paragraph numbered 92.

29. With respect to paragraph numbered 93, M&D Star Drug denies that subject matter jurisdiction exists in Ohio.

30. With respect to the averments contained in paragraph numbered 94, M&D Star Drug denies that personal jurisdiction exists in Ohio.

31. With respect to paragraph numbered 95, M&D Star Drug denies that venue is proper in Ohio.

32. In response to paragraph numbered 96, M&D Star Drug admits that prescription opioids can reduce pain, help have benefits when used properly, and pose certain risks when misused or abused.

33. In response to paragraph numbered 97, M&D Star Drug admits that prescription opioid medications are regulated by Federal and State governmental authorities. To the extent

those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

34. Averments in paragraph numbered 98 which relate to “Marketing Manufacturer Defendants” are directed to Defendants other than M&D Star Drug, and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them. M&D Star Drug denies the remaining averments in paragraph numbered 98.

35. The averments in paragraphs numbered 99 through 161 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

36. To the extent the averments contained in paragraph numbered 162 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent those averments are directed to M&D Star Drug, M&D Star Drug admits that it has a common law duty to exercise reasonable care under the totality of the circumstances. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

37. In response to paragraph numbered 163, M&D Star Drug admits that prescription opioid medications are regulated by Federal and State governmental authorities, but denies that

such regulation creates statutory duties in a tort context or reflects the “standard of care” for M&D Star Drug.

38. In response to paragraph numbered 164, M&D Star Drug admits that prescription opioid medications are regulated by Federal and State governmental authorities, but denies that such regulation creates statutory duties in a tort context or reflects the “standard of care” for M&D Star Drug. This paragraph states legal conclusions as to which no response is required. To the extent that a response is found to be required, M&D Star Drug denies the averments of the paragraph to the extent they are inconsistent with governing law. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

39. With respect to the averments contained in paragraph numbered 165, M&D Star Drug admits that prescription opioid medications are regulated by Federal and State governmental authorities, but denies that such regulation creates statutory duties in a tort context or reflects the “standard of care” for M&D Star Drug. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

40. To the extent the averments contained in paragraphs numbered 166 through 169 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

41. In response to paragraphs numbered 170 through 177, M&D Star Drug admits that prescription opioid medications are regulated by Federal governmental authorities, but denies that

such regulation creates statutory duties in a tort context or reflects the “standard of care” for M&D Star Drug. Those paragraphs state legal conclusions as to which no response is required. To the extent that a response thereto is found to be required, M&D Star Drug denies the averments to the extent they are inconsistent with governing law. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

42. The averments contained in paragraphs numbered 178 through 185 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

43. In response to paragraphs numbered 186 through 199, M&D Star Drug admits that prescription opioid medications are regulated by State governmental authorities, but denies that such regulation creates statutory duties in a tort context or reflects the “standard of care” for M&D Star Drug. Those paragraphs state legal conclusions as to which no response is required. To the extent that a response is found to be required, M&D Star Drug denies the averments of the paragraph to the extent they are inconsistent with governing law. To the extent that the averments therein can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

44. The averments contained in paragraphs numbered 200 through 236 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star

Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

45. In response to the averments contained in paragraph numbered 237, M&D Star Drug asserts that, at all times relevant to Plaintiff's First Amended Complaint, it had the knowledge possessed and used by members of the pharmacy profession at that time. M&D Star Drug denies Plaintiff's specific averments contained therein as phrased.

46. In response to paragraph numbered 238, M&D Star Drug admits that prescription opioid medications are regulated by Federal governmental authorities, which have published information pertaining to them, but denies that such regulation creates statutory duties in a tort context or reflects the "standard of care" for M&D Star Drug. M&D Star Drug denies Plaintiff's specific averments contained therein as phrased.

47. In response to paragraph numbered 239, M&D Star Drug admits that prescription opioid medications are regulated by Federal governmental authorities, which have published information pertaining to them, but denies that such regulation creates statutory duties in a tort context or reflects the "standard of care" for M&D Star Drug. M&D Star Drug denies Plaintiff's specific averments contained therein as phrased.

48. The averments contained in paragraph numbered 240 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

49. The averments contained in paragraph numbered 241 through 243 are directed to Defendants other than M&D Star Drug and therefore no response by M&D Star Drug is required.

50. To the extent the averments in paragraphs numbered 244 through 246 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

51. The averments contained in paragraph numbered 247 through 256 are not directed to M&D Star Drug and therefore no response by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

52. To the extent the averments contained in paragraph numbered 257 through 263 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

53. The averments in paragraph numbered 264 through 284 are directed to Defendants other than M&D Star Drug and therefore no response by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them.

54. To the extent the averments in paragraph numbered 285 through 293 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks

knowledge sufficient to form a belief as to the truth or falsity of the averments therein and therefore denies them. To the extent those averments are directed to M&D Star Drug, M&D Star Drug denies them.

55. In response to paragraph numbered 294, M&D Star Drug agrees that drug addiction and the misuse and abuse of drugs, including prescription opioid medications, represent a public health crisis. To the extent the averments in paragraph numbered 294 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent that the averments in paragraph numbered 294 are directed to M&D Star Drug, M&D Star Drug denies them.

56. To the extent the averments in paragraph numbered 295 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent that the averments in paragraph numbered 295 are directed to M&D Star Drug, M&D Star Drug denies them.

57. The averments in paragraph numbered 296 through 328 are directed to Defendants other than M&D Star Drug and therefore no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent those averments can fairly be read to express or imply actionable conduct on the part of M&D Star Drug, M&D Star Drug denies them.

58. To the extent the averments in paragraphs numbered 329 through 352 are directed to Defendants other than M&D Star Drug no response to those averments by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific averments and therefore denies them. To the extent that the averments in paragraphs numbered 329 through 352 are directed to M&D Star Drug, M&D Star Drug denies them.

59. The claims and allegations in paragraph numbered 353 through 379 are directed to Defendants other than M&D Star Drug and therefore no response to those allegations by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific allegations and therefore denies them.

60. To the extent the claims and allegations in paragraphs numbered 380 through 408 are directed to Defendants other than M&D Star Drug no response to those allegations by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific allegations and therefore denies them. To the extent that the allegations in paragraphs numbered 380 through 408 are directed to M&D Star Drug, M&D Star Drug denies them. Those paragraphs state legal conclusions as to which no response is required. To the extent that a response is found to be required, M&D Star Drug denies the allegations to the extent they are inconsistent with governing law.

61. Plaintiff's Lanham Act claim has been dismissed by the Court, and therefore, no response is required to Plaintiff's allegations contained in paragraphs numbered 409 through 418. To the extent that a response is found to be required, M&D Star Drug lacks sufficient knowledge

to form a belief as to the truth or falsity of the allegations and therefore denies same. To the extent that the allegations in paragraphs numbered 409 through 418 are directed to M&D Star Drug, M&D Star Drug specifically denies them.

62. The claims and allegations in paragraphs numbered 419 through 450 are directed to Defendants other than M&D Star Drug and therefore no response to those allegations by M&D Star Drug is required. To the extent that a response is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations and therefore denies them.

63. To the extent the claims and allegations in paragraphs numbered 451 through 464 are directed to Defendants other than M&D Star Drug no response to those allegations by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific allegations and therefore denies them. To the extent that the allegations in paragraphs numbered 451 through 464 are directed to M&D Star Drug, M&D Star Drug denies them. Those paragraphs state legal conclusions as to which no response is required. To the extent that a response is found to be required, M&D Star Drug denies the allegations to the extent they are inconsistent with governing law.

64. With respect to the claims and allegations in paragraphs numbered 465 through 478, the Court has Dismissed Plaintiff's Negligence Per Se claim related to the Oklahoma Uniform Controlled Dangerous Substance Act; the federal Controlled Dangerous Substance Act; and the Federal Food, Drug, and Cosmetic Act. To that extent, no response to Plaintiff's allegations regarding those claims is required of M&D Star Drug. M&D Star Drug denies the remainder of the allegations in those paragraphs. Those paragraphs state legal conclusions as to which no

response is required. To the extent that a response is found to be required, M&D Star Drug denies the allegations to the extent they are inconsistent with governing law.

65. To the extent the claims and allegations in paragraphs numbered 479 through 493 are directed to Defendants other than M&D Star Drug no response to those allegations by M&D Star Drug is required. To the extent that a response thereto is found to be required, M&D Star Drug lacks knowledge sufficient to form a belief as to the truth or falsity of the specific allegations and therefore denies them. To the extent that the allegations in paragraphs numbered 479 through 484 are directed to M&D Star Drug, M&D Star Drug denies them.

66. In Response to Plaintiff's Prayer for Relief, M&D Star Drug states that the prayer for recovery set forth in Plaintiff's First Amended Complaint speaks for itself. To the extent Plaintiff's Prayer for Relief is directed to Defendants other than M&D Star Drug, no response to those averments by M&D Star Drug is required. To the extent Plaintiff's Prayer for Relief is directed to M&D Star Drug, M&D Star Drug denies them.

AFFIRMATIVE DEFENSES

Having answered the allegations of Plaintiff's First Amended Complaint, and having denied any liability whatsoever, M&D Star Drug further denies any allegations that have not been expressly admitted and sets forth below its affirmative defenses. By setting forth these defenses, M&D Star Drug does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, M&D Star Drug does not intend these defenses to be, nor shall they be construed as, an acknowledgement that any particular issue or subject matter is relevant to Plaintiff's allegations. M&D Star Drug does not admit or acknowledge that it bears the burden of proof or burden of persuasion with respect to any such defense. Upon completion of discovery, if the facts warrant, M&D Star Drug may withdraw any

of these defenses as may be appropriate. M&D Star Drug reserves the right to (i) rely on any other applicable defenses set forth in any Answer or listing of affirmative defenses of any other M&D Star Drug in this Action, (ii) rely on any other defenses that may become apparent during fact or expert discovery in this matter, and (iii) to amend its Answer to assert any such defenses.

1. The Plaintiff's First Amended Complaint fails to state a claim upon which relief may be granted, fails to state facts sufficient to constitute the purported causes of action, and fails to plead a legally cognizable injury.
2. Plaintiff's claims are barred by the applicable statutes of limitation.
3. Plaintiff's claims are barred by the doctrine of laches.
4. Plaintiff's claims are barred by any applicable statutes of repose.
5. Plaintiff's claims are barred or limited for lack of standing.
6. Plaintiff's claims are barred by the doctrine of primary jurisdiction.
7. Plaintiff's claims are barred by the voluntary payment doctrine.
8. Plaintiff's claims are barred by the doctrine of unclean hands.
9. Plaintiff's claims are barred by the doctrine of *in pari delicto*.
10. Venue may be improper and/or inconvenient in this Court.
11. Plaintiff's claims are not ripe and/or have been mooted.
12. Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers.
13. Plaintiff's claims and damages are barred or limited, in whole or in part, by the political question and separation of powers doctrines and because its state-law claims implicate issues of statewide importance that are reserved for state regulation.

14. Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on M&D Star Drug.

15. Plaintiff's claims are barred because Plaintiff is not the real parties in interest.

16. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity to bring its claims, including claims maintained, even indirectly, on behalf of its citizens and/or claims brought as *parens patriae*.

17. Plaintiff's claims are barred to the extent M&D Star Drug has valid defenses which would bar recovery by those persons on whose behalf Plaintiff seeks recovery.

18. Plaintiff's claims are subject to all defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf Plaintiff seeks to recover.

19. Plaintiff has failed to comply with the requirement that it identify each patient in whose claim(s) they have a subrogation interest and on whose behalf it has incurred costs.

20. Plaintiff fails to plead that it reimbursed any prescriptions for any opioid dispensed by M&D Star Drug that harmed patients and should not have been written, that M&D Star Drug's alleged improper conduct caused any health care provider to write any ineffective or harmful opioid prescriptions, or that any prescription was unauthorized, medically unnecessary, ineffective, harmful, or caused any of the injuries or harms for which Plaintiff seeks recovery.

21. Plaintiff's claims are barred by the doctrines of estoppel, waiver, and/or ratification.

22. Plaintiff's claims against M&D Star Drug do not arise from the same transactions or occurrences as their claims against other defendants, as required for joinder of parties.

23. Plaintiff failed to join all necessary and indispensable parties, including without limitation the DEA, health care providers, prescribers, patients, and other third parties whom

Plaintiff alleges engaged in or contributed to the prescription, dispensing, diversion, or use of opioids.

24. M&D Star Drug denies all types of causation, including without limitation cause in fact, proximate cause, efficient proximate cause, and producing cause, as to the claims asserted against M&D Star Drug.

25. Plaintiff's claims are barred, in whole or in part, because M&D Star Drug did not proximately cause the Plaintiff's alleged damages, and because the acts of other persons, including without limitation individuals engaged in the illegal sale and/or use of opioids, intervened between M&D Star Drug's acts and Plaintiff's alleged harms.

26. Plaintiff's claims are barred to the extent they are based on the intentional criminal acts of third parties, which M&D Star Drug had no duty to control or prevent and which act as superseding and/or intervening causes that extinguish any liability.

27. Plaintiff's claims are barred because its alleged injuries and damages resulted from intervening and/or superseding causes, and any act or omission by M&D Star Drug was not the proximate and/or producing cause of Plaintiff's alleged injuries and damages.

28. Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages, if any, were due to illicit use or abuse of the medications at issue by the medication users.

29. Plaintiff's claims are barred to the extent its alleged injuries and damages were caused or contributed to by the negligence or conduct of Plaintiff and/or third parties over whom M&D Star Drug had no control and for whom it is not responsible.

30. Plaintiff's claims are barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bar Plaintiff from recovering payments that it allegedly made on

behalf of its citizens to reimburse any expenses for health care, pharmaceutical care, and/or other public services.

31. The alleged injuries and damages asserted by Plaintiff are too remote and/or speculative from the alleged conduct of M&D Star Drug to be a basis for liability as a matter of law and due process and derive solely from the claims of others.

32. Plaintiff would be unjustly enriched if allowed to recover on any of its claims.

33. Plaintiff's claims are barred because Plaintiff suffered no injuries or damages as a result of any action by M&D Star Drug.

34. Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by unforeseeable or uncontrollable forces over which M&D Star Drug had no control, including without limitation pre-existing or unrelated medical conditions.

35. Plaintiff's claims are barred, in whole or in part, because its alleged injuries or damages were caused by the misuse of the medications involved, by failure to use the medications properly, by the alteration, modification, or criminal misuse of medications, and/or the improper prescription of medications by third parties over whom M&D Star Drug had no control.

36. Plaintiff's claims are barred, in whole or in part, because neither the users of the subject prescription medications nor their prescribers relied to their detriment upon any statement by M&D Star Drug in determining to use or prescribe the subject prescription medications.

37. Plaintiff's claims are barred in whole or in part under the learned intermediary doctrine.

38. Any injuries and/or damages sustained by Plaintiff were caused, in whole or part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff are barred or, alternatively, should be diminished according to its own fault.

39. Any recovery by Plaintiff may be barred or limited by the principle of comparative or contributory fault.

40. Any recovery by Plaintiff may be barred or limited by the principles of informed consent and/or assumption of the risk, whether primary, express, or implied.

41. M&D Star Drug asserts its right to a proportionate reduction, based on the negligence or other conduct of any settling tortfeasor, responsible third party, or plaintiff, of any damages found against M&D Star Drug. 23 O.S. §15.

42. Plaintiff's claims are barred to the extent its alleged damages are speculative, uncertain, or hypothetical.

43. Plaintiff's damages, if any, were caused by the direct and proximate negligence or other conduct of entities or persons other than M&D Star Drug, and in the event M&D Star Drug is found liable to Plaintiff, M&D Star Drug will be entitled to indemnification, contribution and/or apportionment.

44. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or with reasonable certainty will indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source or any other applicable law.

45. In the event of liability against M&D Star Drug (which liability is specifically denied), a percentage of the tortious conduct that proximately caused Plaintiff's injury or loss is attributable to (1) each of the Plaintiff; (2) other parties from whom Plaintiff seek recovery; and (3) persons from whom Plaintiff do not seek recovery in this action, including but not limited to opioid prescribers, their associates, and employers, including hospitals; non-party manufacturers of prescription opioids; non-party distributors of prescription opioids; non-party pharmacies and

pharmacists employed or formerly employed by those pharmacies; other individuals or entities involved in the manufacture, import, distribution, diversion, procurement, sale, dispensing, use, misuse, or abuse of prescription opioids and/or other medications or illegal drugs; delivery services; federal, state, and local government entities; health insurers and pharmacy benefit managers; and any other individuals or entities identified by Plaintiff or any other defendant as a non-party whose tortious conduct proximately caused Plaintiff's injury or loss. See Okla. Stat. tit. 23 §§13-14.

46. If M&D Star Drug is found liable for Plaintiff's alleged injuries and losses (which liability is specifically denied), the facts will show that any recovery by Plaintiff must be reduced pursuant to 23 O.S. §§13-14 to account for the acts or omissions attributable to Plaintiff.

47. Plaintiff failed or refused to exercise reasonable care and diligence to avoid loss and minimize damages and may not recover for losses that could have been prevented by reasonable efforts on its part, or by expenditures which might reasonably have been made. Recovery, if any, should therefore be reduced by Plaintiff's failure to mitigate damages, if any.

48. Plaintiff's claims are barred or limited by the economic loss rule.

49. Plaintiff's claims are barred or limited by the free public services and/or municipal cost recovery doctrine.

50. Plaintiff's claims are barred to the extent they relate to M&D Star Drug's or other defendants' alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Oklahoma or that of any other state whose laws may apply.

51. The damages which Plaintiff may be entitled to recover if liability is established (which liability is specifically denied) are capped pursuant 23 O.S. § 9.1.

52. Any damages that Plaintiff may recover against M&D Star Drug must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject prescription medications, or damages recovered or recoverable by other actual or potential Plaintiff. Any damages that Plaintiff may recover against M&D Star Drug must be reduced to the extent they unjustly enrich Plaintiff.

53. Plaintiff's claims are barred to the extent they rely, explicitly or implicitly, on a theory of market-share liability.

54. To the extent Plaintiff attempt to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

55. Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Due Process or Ex Post Facto clauses of the United States or Oklahoma constitutions.

56. Defendant's rights under the Due Process Clause of the U.S. Constitution and applicable state constitutions or statutes are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff's use of a contingency fee contract with private counsel.

57. Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Dormant Commerce Clause of the United States Constitution.

58. Plaintiff's claims are preempted by federal law, including without limitation the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA").

59. M&D Star Drug's conduct conformed with the FDCA and the requirements of the FDA, and the activities of M&D Star Drug alleged in Plaintiff's First Amended Complaint

conformed with all state and federal statutes, regulations, and industry standards based on the state of knowledge at the relevant time(s) alleged in the Complaint.

60. Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013).

61. Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

62. To the extent Plaintiff asserts claims that depend on violations of federal law, including any claims of a "fraud on the FDA" with respect to the Manufacturer Defendants' disclosure of information related to the safety of their medications at issue, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

63. To the extent Plaintiff assert claims that depend on violations of federal law, including any claims of "fraud on the DEA" with respect to M&D Star Drug's compliance with statutes or regulations administered and/or enforced by the DEA, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

64. Plaintiff's claims are barred, in whole or in part, by the deference that common law accords discretionary actions by the FDA under the FDCA and discretionary actions by the DEA under the Controlled Substances Act.

65. Plaintiff's claims are barred, in whole or in part, for failure to exhaust administrative remedies.

66. If Plaintiff incurred the damages alleged, which is expressly denied, M&D Star Drug is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing of the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA, and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, distributed, and dispensed.

67. Plaintiff's claims are barred to the extent they are based on any averments involving failure to provide adequate warnings or information because all warnings or information that accompanied the allegedly dispensed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed and/or dispensed without an approved new drug application.

68. M&D Star Drug did not owe or breach any statutory or common law duty to Plaintiff.

69. M&D Star Drug appropriately, completely, and fully performed and discharged any and all obligations and legal duties arising out of the matters alleged in the Complaint.

70. Plaintiff's claims are barred, in whole or in part, because M&D Star Drug complied at all relevant times with all applicable laws, including all legal and regulatory duties.

71. To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish M&D Star Drug's regulatory duties, such informal guidance cannot enlarge

M&D Star Drug's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 et seq.

72. Plaintiff's claims are barred, in whole or in part, because Plaintiff has no private right of action under the relevant laws and regulations.

73. Plaintiff's claims are barred, in whole or in part, by the RESTATEMENT (SECOND) OF TORTS § 402A, cmts. j and k, and RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6.

74. M&D Star Drug is not liable for any statements in the Manufacturer Defendants' branded or unbranded materials.

75. Plaintiff's claims are barred in whole or in part, or are subject to other limitations, by the Oklahoma Affordable Access to Healthcare Act, 63 O.S. § 1-1709, et seq.

76. Plaintiff's nuisance claims are barred to the extent that it lacks the statutory authority to bring a nuisance claim under Oklahoma law.

77. Plaintiff's nuisance claims are barred or limited to the extent that they have been abrogated by Oklahoma law, including but not limited to 76 O.S. § 57.2.

78. Plaintiff's claim of public nuisance is barred or limited because no action of M&D Star Drug involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against the distributor sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of M&D Star Drug is too remote from the alleged injury as a matter of law and due process.

79. Plaintiff's claim for unjust enrichment is barred or limited because M&D Star Drug did not receive and retain any alleged benefit from Plaintiff.

80. Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable Oklahoma statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

81. Plaintiff's claims are barred, reduced, and/or limited to the extent that M&D Star Drug is entitled to a credit or setoff for any and all sums Plaintiff has received in the way of any and all settlements. 12 O.S. §832(H).

82. To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct, Plaintiff has failed to plead fraud with sufficient particularity.

83. Plaintiff fails to plead any actionable misrepresentation or omission made by or attributable to M&D Star Drug.

84. Plaintiff may be barred by the doctrines of res judicata and collateral estoppel from all forms of relief sought in its First Amended Complaint.

85. Plaintiff's claims are barred or limited by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of res judicata and collateral estoppel, failure to fulfill conditions precedent, failure to provide requisite notice, payment, accord and satisfaction, and compromise and settlement.

86. Plaintiff's claims are barred in whole or in part because no conduct of M&D Star Drug was misleading, unfair, or deceptive.

87. Plaintiff's claims may be barred because neither the users, nor the prescribers of the medications dispensed by M&D Star Drug, nor Plaintiff itself, relied to their detriment upon any statement by M&D Star Drug in determining to use the medications at issue.

88. Plaintiff's claims are barred, in whole or in part, by the doctrines of acquiescence, settlement, or release.

89. M&D Star Drug's liability, if any, will not result from its conduct but is solely the result of an obligation imposed by law, and thus M&D Star Drug is entitled to complete indemnity, express or implied, by other parties.

90. In the event of a finding of liability against M&D Star Drug (which liability is specifically denied), its liability for damages is several only, and it can only be liable for the amount of damages allocated to it. 23 O.S. §15.

91. Plaintiff's claims are barred or limited by the Indian Healthcare Improvement Act, the Indian Self-Determination and Education Assistance Act, and/or the Federal Medical Care Recovery Act.

92. This Court lacks subject matter jurisdiction.

93. This Court lacks personal jurisdiction.

94. Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the Due Process clauses of the United States Constitution, the Excessive Fines Clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution, the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, the Sixth Amendment to the United States Constitution, and applicable provisions of the Constitution of Oklahoma or that of any other state whose laws may apply. Any law, statute or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it:

- (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any;
- (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties;
- (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff;
- (4) permits the imposition of punitive damages where the burden of proof is less than clear and convincing evidence;
- (5) permits the imposition of punitive damages without bifurcating the trial and trying all punitive damages issues separately, only if and after a finding on the merits of the liability of the Defendants;
- (6) permits the imposition of punitive damages without any predetermined limit on any such award;
- (7) permits an imposition of punitive damages that allows for multiple punishments for the same alleged act(s) or omission(s);
- (8) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any;
- (9) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendants;

(10) lacks constitutionally sufficient standards to be applied by the trial court in postverdict review of any award of punitive damages or civil penalties;

(11) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties;

(12) would unconstitutionally impose a penalty, criminal in nature, without according to Defendants the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, this State, and any other state whose laws may apply; and

(13) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

95. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

96. Plaintiff's claims for punitive or exemplary damages are barred because Plaintiff cannot prove by clear and convincing evidence that M&D Star Drug was grossly negligent, and M&D Star Drug has neither acted nor failed to act in a manner that entitles Plaintiff to recover punitive or exemplary damages.

97. Plaintiff cannot obtain relief on its claims based on actions undertaken by M&D Star Drug of which M&D Star Drug provided notice of all material facts.

98. Plaintiff's RICO claims are barred, in whole or in part, by the absence of the existence of an "enterprise" for the purposes of RICO liability.

99. Plaintiff's RICO claims are barred, in whole or in part, by the absence of an "association" between Defendant and any other defendant or entity alleged to be part of an "enterprise" for purposes of RICO.

100. Plaintiff's RICO claims are barred, in whole or in part, because Defendant did not participate in any "enterprise."

101. Plaintiff's RICO claims are barred, in whole or in part, because Defendant did not engage in a pattern of racketeering activity under RICO.

102. Plaintiff's RICO claims are barred, in whole or in part, because Defendant did not knowingly agree to facilitate any schemes that includes the operation or management of a RICO enterprise.

103. Plaintiff's claims are barred, in whole or in part, by the absence of a conspiracy, including a lack of agreement to commit any unlawful predicate acts, necessary to establish a valid RICO claim under 18 U.S.C. § 1962(d).

104. Plaintiff's RICO claims are barred, in whole or in part, because Defendant did not commit any predicate acts that may give rise to liability under 18 U.S.C. § 1962.23

105. Plaintiff's RICO claims are barred, in whole or in part, because there are no allegations that Defendant adopted the goal of furthering or facilitating any criminal endeavor as necessary to support plaintiff's civil conspiracy theory of liability.

106. The federal RICO statute is unconstitutionally vague.

107. Plaintiff's alleged damages do not constitute injury to business or property interests cognizable under RICO.

108. Plaintiff's RICO claims are barred, in whole or in part, because the alleged predicate acts, namely failure to report and halt suspicious orders under the Controlled Substances Act, do not qualify as racketeering activity for purposes of RICO.

109. M&D Star Drug is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of the State of Oklahoma or any other state whose substantive law might control the action.

110. M&D Star Drug asserts all applicable defenses under Federal Rules of Civil Procedure 8(c) and 12(b) and/or 12 O.S. § 2012 as investigation and discovery proceeds.

111. M&D Star Drug reserves the right to assert any other defense available under Oklahoma statutes, Oklahoma common law, the Oklahoma Constitution, and/or any other state constitution, statute, or regulation that may apply.

112. To the extent they are not otherwise incorporated herein, M&D Star Drug incorporates as a defense the defenses and arguments raised in the motions to dismiss of the Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants in this case.

113. M&D Star Drug adopts by reference any additional applicable defense pleaded by any other Defendants not otherwise pleaded herein.

Respectfully submitted,

s/ Steven W. Simcoe
Sean H. McKee, OBA #14277
smckee@bestsharp.com
Matthew B. Free, OBA #18055
mfree@bestsharp.com
Benjamin D. Reed, OBA #22696
breed@bestsharp.com
Steven W. Simcoe, OBA #15349
ssimcoe@bestsharp.com
BEST & SHARP
Williams Center Tower 1

One West Third Street, Suite 900
Tulsa, OK 74103
smckee@bestsharp.com
Telephone: (918) 582-1234
Facsimile: (918) 585-9447
Attorneys for Defendant
M&D Star Drug, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of July, 2019, the foregoing Answer of Defendant M&D Star Drug, Inc. was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

s/ Steven W. Simcoe
Steven W. Simcoe